MAY - 2 2001

2. 510(k) SUMMARY
of Safety and Effectiveness
+
SE Comparison Table

Heinz Kurz GmbH Medizintechnik
As required by Section 807.92

2.1 Submitter: [807.92 (a)(1)]

Heinz Kurz GmbH Medizintechnik
Tuebinger Str. 3
D-72144 Dusslingen
Germany
Tel. + 49-7072-91 79 0
Fax + 49-7072-91 79 79
eMail info@kurzmed.de
http://www.kurzmed.de

2.2 Contact Person: [807.92 (a)(1)]

Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands
Tel. +31-20-428 95 91
Fax +31-20-428 94 29
eMail bsi@xs4all.nl

2.3 Date Summary Prepared: [807.92 (a)(1)]
March 14, 2001

2.4 Device Names: [807.92 (a)(2)]

Proprietary	KURZ Upper Eyelid Implant – Platinum-Iridium
Common	Platinum Eyelid Weights
Classification	Weights, Eyelid, External

2.5 Reason for Submission: [807.81(2)]

Material Change

2.6 Modification to Existing Device [807.92(a)(3)]

K 000127 KURZ Pure Gold Upper Eyelid Implant (Oberascher)
Cleared 04/12/00

2.7 Device Description: [807.92(a)(4)]

The KURZ Eyelid Implant – Platinium-Iridium has the shape of an oblong, slightly curved rectangle designed to closely fit the curvature of the eyeball. All edges are rounded and flattened so that practically no bulge is visible over the tarsal region when the eye is closed.

Made of 90% platinium and 10% iridium, the implant has a maximum thickness of 0.8 mm and is approx. 5 – 5.2 mm wide. Five (5) standard sizes accommodate most patients; four (4) special sizes are available for smaller (1) or larger (3) eyes.

Each implant comes with four (4) suture holes for attachment to the tissue just superficial to the tarsal plate with 8-0 permanent **non-absorbable** monofilament sutures.

The platinum/iridium lid weights are identical to the previously cleared devices with the following exceptions:

1. **Material**
   90% platinum + 10% iridium instead of 99.99% pure gold
2. **Thickness**
   0.8 mm instead of 1.0 mm

The indications for use, dimensions such as lengths and width, and the weights for the different sizes are identical or substantially equivalent to the previously cleared device.

2.8 Reasons for Device Modification: [807.92 (d)]

The material change from pure gold to platinum/iridium results in the following improvements:

1. The specific weight of platinum/iridium is higher than that of pure gold; thus it is possible to create thinner lid weights with overall size and width remaining unchanged;
2. Clinical tests have shown platinum/iridium to be more biocompatible than pure gold which may produce postoperative swelling and redness in upper lid in some patients.

2.9 Intended Use: [807.92 (a)(5)]

KURZ Upper Eyelid Implants – Platinum/Iridium are intended for surgical implantation in the upper eyelid. They work by force of gravity to restore a functional blink mechanism in the patient with lagophthalmos resulting from temporary or permanent facial paralysis, specifically the orbicularis oculi muscle. This paralysis may be the result of Bell's palsy or have been caused by surgical trauma to the facial nerve.

Functional defects which may be corrected or avoided with the use of KURZ Upper Eyelid Implants – Platinum/Iridium include inadequate eyelid closure, corneal exposure, serious keratopathy such as ocular irritation, keratitis, corneal abrasion or ulceration. These conditions may result in decreased vision.

The device is intended for exclusive use by qualified surgeons trained in ophthalmic procedures.

The intended use of KURZ Upper Eyelid Implants – Platinum/Iridium is **identical** to that of the previously cleared device.

2.10 Risk Analysis [807.92 (b)(1)]

A complete risk analysis, including special factors that might be associated with the material change to platinum/iridium, was carried out according to FDA-recognized Consensus Standard EN 1441 (1997).

2.11 Industry Standards [807.92 (d)]

KURZ certifies compliance with required ISO/EN/ASTM/ AAMI/ANSI and other device/related standards that apply to the manufacture, packaging, labeling, sterilization, and reprocessing (custom instruments) of subject devices including the validation of these processes.

2.12 MRI Environment [807.92 (d)]

Like other precious metals (gold, titanium), platinum/iridium is MRI-compatible, i.e. no implant movement and/or adverse tissue effects are attributable to MRI-generated heating. The image quality may be impeded or blurred in direct vicinity of the implant so that in some instances two or more views are necessary to see all of the tissue surrounding the prosthesis. To date, no report of adverse effects has come to the attention of the manufacturer.

KURZ recommends strict adherence to the user instructions of magnetic resonance imaging tomographs.

2.13 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]

KURZ Upper Eyelid Implants – Platinum/Iridium have the same intended use as the previously cleared pure gold devices. Clinical tests prove platinum/iridium to be an excellent biocompatible material. The thinner implants, possible as a result of the higher specific weight, improve the cosmetic result of the indicated procedures and offer an alternative choice for patients with gold allergy or sensitivity to this material. No additional characteristics are known that should adversely affect the safety and effectiveness of these implants.

The results of design validation and clinical testing raise no new issues of safety and effectiveness.

2.14 KURZ Upper Eyelid Implant – Platinum/Iridium

COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

DEVICE	Upper Eyelid Implant Pure Gold	Upper Eyelid Implant Platinum/Iridium
Catalog #	Length Width 0.8 g 15.0 / 5.0 mm **4001 003** 1.0 g 15.0 / 5.0 mm **4001 004** 1.2 g 18.0 / 5.0 mm **4001 005** 1.4 g 20.0 / 5.0 mm **4001 006** 1.6 g 20.0 / 5.2 mm **4001 007**	Length Width 0.8 g 15.0 / 5.0 mm **4007 003** 1.0 g 15.0 / 5.0 mm **4007 004** 1.2 g 18.0 / 5.0 mm **4007 005** 1.4 g 20.0 / 5.0 mm **4007 006** 1.6 g 20.0 / 5.2 mm **4007 007**
Special Sizes On Request	0.6 g 1.8 g 2.0 g 2.2 g	Same
Intended Use	Same	Same
Accessories	Stainless Steel Test Weights Cat. # 8000 111 K 001123	Same
Material	Pure Gold (Au 99.99)	90.5% Pure Platinum 9.5% Pure Iridium
Thickness	1 mm	0.8 mm
Weight/Length/ Width	s. Catalog #	Same
Single Use	Yes	Same
Sterile	Yes	Same
Sterilization Method	Gamma Irradiation	Same
Resterilization Permitted	No	Same
Design Comparison	Same	Same - Thinner implant reduces upper eyelid contouring and produces superior cosmetic results
Biocompatibility	Well Documented	Equal to superior
MRI	Compatible	Same
Microwave	No	Same
Contraindication	1. Known allergy to gold and gold alloys 2. Lid closure unsuccessful with trial weights 3. Bell's phenomenon	1. Known allergy to platinum and/or iridium 2. Same 3. Same
Risk Analysis	Yes – EN 1441 (1997)	Same
Safety & Effectiveness of Material Change [807.92 (b)(1)]		Platinium/Iridium is a clinically well-established implant material with excellent biocompatibility. Due to the heavier specific weight, thinner implants produce improved cosmetic results. *Careful attention is to be paid to KURZ instructions.*

Date 3/19/2001 Signature

Uwe Steinhardt
Technical Director

03/14/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Ms. Dagmar Mäser
FDA Liaison for Heinz Kurz GmbH Medizintechnik
C/O Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K011115
Trade/Device Name: KURZ Upper Eyelid Implant-Platinum-Iridium
Regulatory Class: Unclassified
Product Code: 86 MML
Dated: April 10, 2001
Received: April 12, 2001

Dear Ms. Mäser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K011115

Device Name KURZ Upper Eyelid Implant – Platinum-Iridium

Classification Weights, Eyelid, External

Product Code 86 MML **Class II** **21 CFR: None to Date**

INDICATIONS FOR USE

Absence of or defective innervation of orbicularis oculi muscle (lagophthalmos) due to peripheral facial paralysis, for example:

- Idiopathic facial paralysis lasting longer than two (2) months;
- Facial paralysis from herpes zoster virus for longer than two (2) months;
- Concurrent with surgical reanimation of facial nerve, i.e. primary nerve suturing, rerouting, nerve interposition, VII/XII nerve anastomosis, free muscle graft;
- Injury to facial nerve from trauma or tumor resection without possibility of nerve reanimation
- Cosmetic.

SURGICAL OBJECTIVE

Optimization of lid closure through addition of weight to upper lid. By restoring the functional blink mechanism, this procedure prevents dehydration of corneal epithelium resulting from defective hydration and complications such as erosion, ulcers, perforations, reduction of visual acuity, and even blindness.

KURZ Upper Eyelid Implants – Platinium-Iridium are intended for exclusive use by qualified medical personnel trained in ophthalmic surgical techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)

Susan Gouge

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K011115

V